

### REMARKS

Favorable reconsideration of this application is requested in view of the foregoing amendment and the following remarks. New Claim 48 has been added. Therefore, claim 1-46 and 48 are currently pending.

Claim 1 is currently amended to indicate that the rehydration step occurs in the presence of an aqueous environment. Support for the amendment of claim 1 can be found on page 3 of the International Application. No new matter has been added with the current amendment.

Claims 1-46 have been rejected as being unpatentable over "Studies on the Hydration of Natural Anhydrite" by Murakami et al. in view of Soviet Patent Document No. 345,098 and further in view of U.S. Patent No. 5,248,487 to Bold et al.

Claim 1 of the present application, as amended, claims a method of producing surgical grade calcium sulfate by first forming an initial calcium sulfate di-hydrate from synthetic constituents. The initial calcium sulfate di-hydrate is then dehydrated to form calcium sulfate anhydrite. Finally, the calcium sulfate anhydrite is subsequently rehydrated in the presence of an aqueous environment which allows the calcium sulfate di-hydrate to crystallize out.

The present invention concerns surgical grade calcium sulfate, and particularly such material for use as a bone void filler. It is imperative that such a material have a very high purity and hence the material is made from synthetic constituents. As noted in the specification on page 1, second paragraph, conventional techniques produce materials with high surface area which has a high water demand and therefore produce a low strength material when set. Such a material has a short dissolution rate when implanted. In the present invention, the calcium sulfate di-hydrate formed from synthetic constituents is dehydrated to form calcium sulfate anhydrite. The formed anhydrite is soluble in contrast to insoluble anhydrite as derived from natural sources such as natural anhydrite. In present claim 1, the anhydrite is rehydrated with water to allow subsequent calcium sulfate di-hydrate to crystallize out. The subsequent di-hydrate which crystallizes out has a relatively low specific surface area and, hence, water requirement.

In contrast, the Murakami reference relates to the difficulties of hydrating natural anhydrite. The anhydrite of Murakami will therefore be of the insoluble "dead burnt" type. This anhydrite will not be synthetically formed and thus surgical grade which, in turn, would not be suitable for use in the method of present claim 1. Further, the hydration of the anhydrite in Murakami is achieved through a salt

solution such as a 15% solution of ammonium nitrate with continuous stirring. The present claim 1 does not require stirring, as is shown by the use of the expression "immersing" in the amended claim 1.

There are significant differences in the process described in Murakami and what is recited in claim 1. Murakami does not concern synthetic constituents. In addition, the high proportions of salt described in Murakami will affect the purity of the final product. Therefore, Murakami is quite different from the method of claim 1 and one of ordinary skill in the art would not look to Murakami to produce the surgical grade calcium sulfate as described in claim 1.

The Soviet document to Drozin does not cure the deficiencies of the Murakami reference. Specifically, Murakami does not teach one of ordinary skill in the art the method of recited claim 1. Drozin relates to preparing insoluble anhydrite. Drozin employs a very high concentration of salt (>70% Calcium Chloride) along with heating and stirring. The product of the Drozin reference would result in impurities from the use of the high concentration of salt. In addition, the Drozin process teaches stirring the solution. In contrast, present claim 1, as amended, calls for rehydration to take place through "immersing." Immersing in contrast to stirring produces larger crystal sizes which have a lower surface area and thus a low water requirement. Accordingly, Drozin does not remotely relate to surgical grade materials. Instead Drozin relates to producing insoluble anhydrite from natural materials which would thus be wholly unsuited to use in surgical grade applications.

As shown above, Murakami does not disclose, teach or suggest the method recited in present claim 1. Specifically, claim 1 calls for using a calcium anhydrite that was synthetically obtained from dehydrating calcium sulfate di-hydrate. Drozin does not disclose calcium sulfate di-hydrate being formed from synthetic constituents. Therefore, one of ordinary skill in the art would not look to Murakami in view of Drozin for a method of producing surgical grade calcium sulfate. Accordingly, claim 1 is patentable over the cited references and withdrawal of the rejection is respectfully requested.

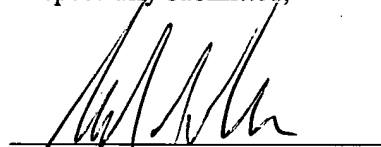
Claims 2-46 depend from claim 1. These dependent claims are patentably distinguished from the cited references for the same reasons as the claims from which they depend. Specifically, U.S. Patent No. 5,248,487 to Bold et al. relates to a method of forming hemihydrate from di-hydrate and is not relevant to present dependent claims. Furthermore, the Bold reference proposes material being formed from flue gas desulfurization units. Such materials are clearly far from surgical grade. Therefore, the Bold reference does not teach the features of the independent claims in view of the claim from which they depend. Since independent claim 1 is non-obvious under 35 U.S.C. § 103, then all claims depending from claim 1 are also non-obvious. As such, withdrawal of the rejection of these claims is

respectfully requested.

In view of the foregoing amendment and remarks, claims 1-46 and 48 are now in condition for allowance. A favorable response to this Amendment in the form of a Notice of Allowance is hereby solicited.

Dated: 8/25/03

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Michael A. Miller', is written over a horizontal line.

Michael A. Miller

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